

THE TERATOLOGY SOCIETY

Birth Defects Insights

Judging By the Label: Why This Gathering Is Labeled ‘Premier’ For Your Scientific Career

By Tacey E.K. White, PhD, Teratology Society Vice President

In my day-to-day job I help pharmaceutical companies plan and interpret developmental toxicity information in animals, and assess the risks for these effects in women and men taking these medications. Understanding the mechanisms underlying effects in animals is fundamental to assessing whether effects would happen in humans. Part of my role also includes helping companies develop pregnancy labeling content for their medications. Sounds cut and dry, right? Not so much...

Major changes to the Food and Drug Administration’s (FDA) pregnancy labeling rule have just been finalized and will go into effect in June of this year. The changes will be challenging for companies to comply with, particularly as they revise labels that may be up to 14 years old. For decades the FDA had been aware of significant problems with the system used to categorize medications for use in pregnancy. As far back as 1992, the group I represent as Vice President, the Teratology Society, expressed concerns, noting that the Pregnancy Category system was often misinterpreted by prescribers, leading to poor patient counseling or under-treatment of serious diseases in pregnancy. The new FDA Pregnancy and Lactation Labeling Rule should be a major improvement with the inclusion of more descriptive risk statements, clinical and mode of action data in addition to animal data, and statements about the risks of untreated conditions. But, how do we bring this all together exactly?

Could the answers lie in Canada? Wait... That doesn’t make sense...or does it?!

It sure does! As the world’s premier group of scientists in the birth defects research field prepare to gather in Montreal, Canada at the end of this month for the [Teratology Society’s 55th Annual Meeting](#), much of the excitement surrounds the pregnancy and lactation labeling workshop, *“The Pregnancy and Lactation Labeling Rule: It’s Here, Now What?”* Workshop attendees will be able to hear directly from regulators on the changes to the labeling rule, tips for implementing these changes and how the content will be interpreted by clinicians – invaluable information as we all try to navigate these changes!

In addition, meeting symposia looking at mechanisms of birth defects and how they translate to humans will be crucially important, including *“Are Human Skeletal Malformations the Result of Embryonic Arterial Dysgenesis?”* This symposium brings together basic research in embryology with clinical observations on skeletal malformation etiology in humans, and is a prime example of the ability of the diverse membership of the Teratology Society to produce translational research on human birth defects. This information is directly applicable to my own basic research on developmental toxicity of the anti-

malarial agent, artesunate, in particular the ability to make predictions about human risk for the skeletal defects observed in animal studies.

What? You want genetics, you say? We've got that covered too! The "*Genetic and Environment Interactions of Common Malformations*" symposium explores the contribution of genetics and various environmental factors to the development of several common malformations including congenital club foot, heart defects and infantile hydrocephalus. The information allows clinicians to develop and communicate prevention strategies to patients who may be at high risk for having babies with these malformations based on family history. The information is also important for basic researchers seeking to understand the mechanisms underlying the production of these birth defects.

My Big, Fat Scientific Family

The cross-disciplinary nature of our members (bench scientists, clinicians, epidemiologists, regulators) means that I can get to know researchers who are outside of my research sector, but who share a common goal of understanding and preventing birth defects and problems with fertility, all coming at it from different points of view. Without the Teratology Society, I would never have had the chance to meet these researchers, let alone discuss issues of mutual interest and potentially collaborate on projects that lead to important new discoveries. The society is small so, over the years, we have all established deep relationships with other members and getting together every year is like getting together with family. I hope you will join us this year for what is shaping up to be a great meeting!

Scientists interested in learning more about the Teratology Society's research, attending the annual meeting, as well as becoming a member are encouraged to visit www.Teratology.org. Members include those specializing in cell and molecular biology, developmental biology and toxicology, reproduction and endocrinology, epidemiology, nutritional biochemistry, and genetics, as well as the clinical disciplines of prenatal medicine, pediatrics, obstetrics, neonatology, medical genetics, and teratogen risk counseling. In addition, it publishes the scientific journal, [Birth Defects Research](http://www.BirthDefectsResearch.org).

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About The Author

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